(f) A supervising dentist shall not delegate the monitoring of nitrous oxide/oxygen inhalation analgesia to a licensed dental hygienist or to a registered dental assistant if a patient is taking any medications, whether prescribed by the dentist or by another licensed practitioner, that in the professional judgment of the dentist may potentiate the effects of the nitrous oxide/oxygen inhalation analgesia, or may change the level of consciousness of the patient.

(g) The supervising dentist shall be responsible for ensuring that the patient records are documented to reflect the nitrous oxide and oxygen flow rates and the analgesia duration and clearing times.

(h) The supervising dentist shall personally discharge the patient following the administration of nitrous oxide/oxygen inhalation analgesia.

(i) The delegation of the monitoring of nitrous oxide/oxygen inhalation analgesia to a registered dental hygienist pursuant to N.J.A.C. 13:30-1A.2 or registered dental assistant pursuant to N.J.A.C. 13:30-2.4 without first having met the minimum standards of training and procedures as stated therein shall constitute a deviation from normal standards of practice required of a licensee.

(a)

DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS
Certified Midwives
Proposed Repeals: N.J.A.C. 13:35-2A.1, 2A.2, 2A.4, 2A.5, 2A.6, 2A.8, 2A.9 and 2A.10
Proposed New Rules: N.J.A.C. 13:35-2A.1 through 2A.5, 2A.7, 2A.8, 2A.10, 2A.11, 2A.12, 2A.15, 2A.16 and 2A.17
Proposed Recodifications with Amendments: N.J.A.C. 13:35-2A.3 as 2A.6, 2A.7 as 2A.9 and 2A.11 as 2A.14

Authorized By: State Board of Medical Examiners, William Roeder, Executive Director.

Authority: N.J.S.A. 45:9-2 and 45:10-22.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2002-354.

Take notice that, pursuant to N.J.S.A. 52:14B-4(a)3, the New Jersey State Board of Medical Examiners (the Board) will hold a **public hearing** on the notice of proposal that follows. The hearing shall be held by the Board as set forth below:

Date: Friday, October 25, 2002
Time: 10:00 A.M.
Location: Robert Wood Johnson University Hospital at Hamilton
One Hamilton Health Place
Hamilton, NJ 08690

The public hearing shall be conducted by a hearing officer. A verbatim transcript of the hearing will be prepared by a certified stenographic reporter. Interested parties may obtain a copy of the transcript by ordering it directly from the reporter at the hearing or thereafter. Requests to speak should be submitted in writing to William V. Roeder, Executive Director, State Board of Medical Examiners, PO Box 183, Trenton, New Jersey 08625-0183 no later than one week prior to the public hearing. Specific presentation times will be assigned. Individual presentations will be limited to five minutes. Those who do not preregister to speak will be given an opportunity to speak only if time permits. Individual speakers are requested to provide at least 16 copies of their prepared remarks to the hearing officer on the day of the public hearing.

Submit comments by December 6, 2002 to:
William Roeder, Executive Director
State Board of Medical Examiners
PO Box 183
Trenton, NJ 08625-0183

The agency proposal follows:

Summary

Pursuant to its rulemaking powers found in N.J.S.A. 45:9-2, and specifically N.J.S.A. 45:10-22, the State Board of Medical Examiners (the Board) proposes amendments to N.J.A.C. 13:35-2A concerning the licensure and practice of midwives.

N.J.S.A. 45:10-1 et seq. grants the Board the authority to regulate the practice of midwifery. This statute also imposes qualifying requirements for licensure that include completion of a certificate or diploma program from a school of midwifery or a maternity hospital. For many years, the only individuals who applied and qualified pursuant to the statutory requirements were those who completed certified nurse midwifery programs. These programs require that students hold licensure as a registered nurse and qualified graduates to take an examination for certification as certified nurse midwife (CNM). Correspondingly, the Board adopted rules that dealt solely with the practice of CNMs and established a Certified Nurse Midwife Liaison Committee (the Committee) to assist the Board in regulating midwifery. With the advent of applications from midwives who are not registered nurses, the Board has decided to amend its rules on the practice of midwifery to include the new classifications of certified midwives (CM) and certified professional midwives (CPM). The Board also proposes changes to its rules to reflect changes in the practice of midwifery, to clarify language and to grant licensees authority to perform limited ultrasound examinations, colposcopies and circumcisions.

Existing N.J.A.C. 13:35-2A.1 is entitled "Certified Nurse Midwife practice" and deals with the licensure and practice of CNMs. The Board proposes to repeal this rule and proposes a new rule titled "Midwifery practice" to address the practice of midwifery by CNMs, CMs and CPMs. New subsection (a) states that the subchapter is designed to protect the health and safety of the public by licensing midwives. Subsection (b) states that the subchapter prescribes standards for midwife licensure and renewal and suspension or revocation of licensure.

N.J.A.C. 13:35-2A.2 is a proposed new rule which provides definitions for the following terms: "affiliated physician," "Board," "certified midwife," "certified professional midwife," "certified nurse midwife," "clinical guidelines," "Committee" and "licensee."

N.J.A.C. 13:35-2A.3 is a proposed new rule which addresses the Midwifery Liaison Committee. Subsection (a) states that the Midwifery Liaison Committee shall consist of eight members. The Committee shall include one certified nurse midwife, one certified professional midwife, one certified midwife and two other midwives. All midwives must be licensed by the Board. The Committee also must have one certified nurse midwife who is a member of the Board and two physicians, one of whom must be a member of the Board and another who must be Board-certified by either the American Board of Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology or any certification organization with comparable standards. Subsection (b) states that the Board will appoint each member of the Committee for a term of three years. Subsection (c) states that Committee functions include advising the Board in the evaluation of applicants for licensure and prescriptive authority, investigating complaints against licensees, approving professional education programs and advising the Board in drafting rules regarding midwifery practice.

Existing N.J.A.C. 13:35-2A.2, which sets forth requirements for licensure of certified nurse midwives is proposed for repeal, and replacement with new N.J.A.C. 13:35-2A.4, which sets forth requirements for a license to practice midwifery. Proposed new subsection (a) requires that an applicant submit to the Committee: an application for licensure; proof that the applicant is at least 18 years old; an official transcript from a midwifery program; a notarized copy of certification from either the American College of Nurse Midwives (ACNM), the American College of Nurse Midwives Certification Council (ACC) or the North American Registry of Midwives (NARM); the applicant's curriculum vitae; three signed, dated and notarized photographs of the applicant; and the application fee as set forth in N.J.A.C. 13:35-6.13(a)6i. Proposed new subsection (b) requires an applicant to submit the initial licensing fee once he or she has been approved for licensure.

Proposed new N.J.A.C. 13:35-2A.5 deals with the independent practice of midwives. Subsection (a) states that certified nurse midwife and certified midwife practice includes the provision of maternity care and well woman care within a healthcare system which provides for consultation, referral and collaboration. This practice also includes administering and dispensing medications listed in clinical guidelines, if a licensee does not have prescriptive authority, and prescribing, ordering, administering or dispensing medications for licensees that have prescriptive authority pursuant to N.J.A.C.

13:35-2A.14. Subsection (b) requires certified nurse midwives and certified midwives to conduct their practice pursuant to the standards of the American College of Nurse Midwives in Standards for the Practice of Nurse Midwifery (1993), available from the American College of Nurse Midwives, 818 Connecticut Ave., Suite 900, Washington, D.C. 20006. The Standards for the Practice of Nurse Midwifery requires that a CNM or CM practice within a health care system that provides for consultation, collaborative management or referral as indicated by the health status of the patient. A CNM or CM is required to collect and assess patient care data, develop and implement a plan of management, and evaluate the outcome of care and practice. Subsection (c) states that the practice of certified professional midwives includes the provision of maternity care within a health care system which provides for consultation, referral and collaboration, and the dispensing of medications listed in the clinical guidelines. Subsection (d) requires certified professional midwives to conduct their practice pursuant to standards set forth by the North American Registry of Midwives in Midwifery Model of Care (2000) available from the North American Registry of Midwives, 5257 Rosestone Drive, Lilburn, GA 30047. The Midwifery Model of Care is based on the belief that pregnancy and birth are normal life events. It requires the CPM to: monitor the physical, psychological, and social well-being of the mother throughout the childbearing cycle; provide the mother with education, counseling, prenatal care, hands-on assistance during labor and delivery, and postpartum support; minimize technological interventions; and identify women who require obstetrical attention.

Existing N.J.A.C. 13:35-2A.3 is proposed for recodification as N.J.A.C. 13:35-2A.6. The existing title of the rule is "Minimum conditions of practice." The Board proposes to change this title to "Affiliated physicians; clinical guidelines." Proposed new subsection (a) requires a licensee to enter into an affiliation with a New Jersey licensed physician prior to beginning practice as a midwife. The affiliated physician must either hold hospital privileges in operative obstetrics/gynecology, have a binding agreement with a physician who holds operative privileges in operative obstetrics/gynecology or, if the licensee limits his or her practice to non-obstetrical, hold hospital privileges in gynecology. Existing subsection (a) is proposed for recodification as subsection (b). The rule is proposed for amendment to indicate that the Board now refers to the agreement between a licensee and an affiliated physician as a "clinical guideline" to reflect that the rules no longer regulate solely CNMs and to point out that the clinical guideline outlines the licensee's scope of practice. The provisions of the rule which required the affiliated physician to have hospital privileges and which outlined the requirements for the clinical guidelines are incorporated into new subsections (a) and (c). Proposed new subsection (c) requires the clinical guidelines to set forth: an outline of routine care; procedures the licensee will perform; procedures to follow if risk factors are encountered; the circumstances under which consultation, collaborative management, referral and transfer of care between the licensee and the affiliated physician are to take place; a formulary of the categories of drugs which a certified nurse midwife may order, prescribe, administer or dispense if the certified nurse midwife holds prescriptive authority; a list of medications the licensee can dispense or administer pursuant to directions of a physician if the licensee does not hold prescriptive authority; a mechanism for determining the availability of the affiliated physician for consultation and emergency assistance; and the manner by which emergency care for newborns will be provided. Existing subsection (b) is proposed for recodification as subsection (d). The rule has been amended to require licensees to file a notice identifying affiliated physicians and the physicians' phone number and address prior to beginning practice. Licensees are no longer required to file a copy of the clinical guidelines with the Board. The rule is further amended to require licensees to inform the Board when there is a change in affiliated physicians within 30 days (instead of the current seven days) of the change. Subsection (e) is a proposed new provision which requires licensees to make clinical guidelines available to the Board upon request. Existing subsection (c) is proposed for recodification as subsection (f). The rule is proposed for amendment to clarify its language. Subsection (d) requires CNMs to undergo peer review by the Peer Review Committee of the ACNM. The Board proposes to delete this requirement because it does not believe that it has the statutory authority to require peer reviews. Subsection (e) is proposed for deletion and its provisions are incorporated into proposed new N.J.A.C. 13:35-2A.5. Proposed new subsection (g) states that licensees who practice without clinical guidelines commit professional misconduct as proscribed by N.J.S.A. 45:1-21(e).

N.J.A.C. 13:35-2A.7 is a proposed new rule which deals with biennial renewal. Subsection (a) of the rule requires licensees to renew licensure every two years. Subsection (b) requires applicants for renewal to submit a completed renewal form and the biennial registration fee pursuant to N.J.A.C. 13:35-6.13(a)6v.

Existing N.J.A.C. 13:35-2A.4, Normal antepartum management, is proposed for repeal, and replacement with N.J.A.C. 13:35-2A.8, Antepartum management. Proposed subsection (a) states that a licensee's scope of practice during antepartum stages includes ordering medical therapeutic and diagnostic measures in accordance with clinical guidelines and identifying women with the risk factors outlined in N.J.A.C. 13:35-2A.9.

Existing N.J.A.C. 13:35-2A.5 is proposed for repeal and its provisions are incorporated into new N.J.A.C. 13:35-2A.10.

Existing N.J.A.C. 13:35-2A.6 is proposed for repeal and its provisions are incorporated into proposed new N.J.A.C. 13:35-2A.12 and 2A.13.

N.J.A.C. 13:35-2A.7 is proposed for recodification as N.J.A.C. 13:35-2A.9. The heading of the rule is proposed for amendment to "Management of antepartum women at increased risk." The rule is proposed for amendment to clarify its language; indicate that the rule applies to all licensees, not just CNMs; indicate that the rule deals with affiliated physicians; require licensees to document management plans; and indicate the rule applies to women at increased risk. The rule is further amended to require that management plans be reviewed by the licensee and affiliated physician and revised when necessary.

Existing N.J.A.C. 13:35-2A.7(a)3 and 4 are proposed for deletion. These rules set forth guidelines which classified risk factors as Schedule A or Schedule B. The Board does not believe that classifying risk factors is necessary and will no longer use the Schedule A and Schedule B guidelines. The risk factors outlined as Schedule A and Schedule B in (a)4 are incorporated into new subsection (b).

Subsection (b) of N.J.A.C. 13:35-2A.9 is a new provision which sets forth risk factors that require the management outlined in N.J.A.C. 13:35-2A.9(a). These risk factors include maternal health status, such as: acute or chronic hypertension; congenital or acquired heart disease; anti-phospholipid syndrome; HIV positive or AIDS; chronic renal disease; seizure disorder requiring medications; chronic anemia or hemoglobinopathy; diabetes mellitus; drug addiction; psychosis; asthmatics on daily oral medication; any connective tissue disorder; multiple sclerosis; history of cerebrovascular accident; or history of cancer. These risk factors also include maternal reproductive health history, such as: incompetent cervix; two or more second or third trimester fetal losses; preterm labor or delivery; parity of six or more; previous cesarean delivery; surgery involving the uterine wall; previous placental abruption; previous postpartum blood transfusion; previous cervical surgeries including Loop Electrosurgical Excision Procedures (LEEP); cone biopsies or three or more surgical cervical dilitations; or intra-uterine growth restriction and/or delivery of an infant weighing less than 2,500 grams at 36 weeks or more. Risk factors also include current maternal obstetrical status, such as: obstructive uterine myomata; polyhydramnios or oligohydramnios; isoimmunization; multiple gestation; intrauterine growth restriction; current evidence of fetal chromosome disorder confirmed by amniocentesis and/or congenital anomaly; gestational diabetes; maternal age less than 14 years or more than 40 years; PAP smear indicating dysplasia; placenta previa; medicated pre-term labor; or preeclampsia.

Existing N.J.A.C. 13:35-2A.7(a)5 and 7 are proposed for deletion because the Board is no longer using Schedule A and Schedule B guidelines. N.J.A.C. 13:35-2A.7(a)6 is proposed for deletion and its provisions are incorporated into N.J.A.C. 13:35-2A.9(b). N.J.A.C. 13:35-2A.7(a)8 is proposed for deletion because the Board no longer believes it is necessary to require that all antepartum risk factors require prenatal care in a licensed ambulatory care clinic, licensed hospital or professional office.

N.J.A.C. 13:35-2A.10 is a proposed new rule which sets forth guidelines and requirements for a licensee's scope of practice during the intrapartum stage. Subsection (a) states that a licensee, during the intrapartum stage: manage labor and birth for women not classified as at risk pursuant to N.J.A.C. 13:35-2A.11; can perform immediate screening of newborns and resuscitation of newborns when necessary; perform an episiotomy; repair first and second degree episiotomies and lacerations using local anesthesia. Subsection (b) requires licensees to have at the birth site a person who is trained in Basic Life Support and certified in Neonatal Resuscitation Program by the American Academy of Pediatrics. A licensee is also required to have oxygen, a neonatal bag and mask, adult oxygen mask, suction equipment, IV fluids and oxytoxics at the birth site. Subsection (c) allows CNMs and CMs to repair third degree lacerations upon the direction of an affiliated physician and fourth degree lacerations under the direct supervision of a physician who has hospital obstetrical privileges and to administer pudendal anesthesia in a licensed healthcare facility, which includes birthing centers. Licensees are prohibited from administering pudendal anesthesia in any other setting.

Existing N.J.A.C. 13:35-2A.8, Care of intrapartum women at risk, deals with risk factors during the intrapartum stage and procedures licensees must follow when they encounter such risks. The rule is replaced by proposed N.J.A.C. 13:35-2A.11, Management of intrapartum women at increased risk. The provisions of N.J.A.C. 13:35-2A.8(a), (b) and (c) are incorporated into N.J.A.C. 13:35-2A.11(a) and (b). Proposed new subsection (a) states that if a patient evidences certain risk factors, a licensee may only participate in the birth if the birth takes place in a licensed hospital. Those risk factors are: premature rupture of membranes more than 24 hours before onset of regular contractions; assessment of infant weight less than 2,500 grams or more than 4,500 grams; vaginal birth after previous cesarean delivery; the need for prescriptive medication to induce or augment labor; post-datism (greater than 42 weeks completed gestation); multiple gestation; malpresentation; evidence of chorioamnionitis and pre-term labor less than 37 weeks. The rule requires that, if pre-term labor is less than 34 weeks, the affiliated physician must be present at the birth. Subsection (b) requires a licensee to arrange for the presence of the affiliated physician at the hospital or, if the woman is not in a hospital, the immediate transfer of the woman to a hospital obstetric unit if certain risk factors develop during the intrapartum phase. Those risk factors are: development of hypertension or preeclampsia; non-reassuring fetal heart pattern, unresponsive to conservative measures; prolapse of cord; intrapartum hemorrhage; multiple gestation; malpresentation; or any condition requiring operative intervention.

N.J.A.C. 13:35-2A.12 is a proposed new rule regarding postpartum care. The rule states that a licensee's scope of practice during the postpartum stage includes assessment, treatment and contraceptive services.

Proposed new N.J.A.C. 13:35-2A.13 deals with well woman care. The rule states that a CNM or CM may provide well woman care which includes: gynecological and primary health care screening, assessment and treatment; and contraceptive services.

Existing N.J.A.C. 13:35-2A.9 is proposed for repeal and its provisions are incorporated into new rule N.J.A.C. 13:35-2A.3.

Existing N.J.A.C. 13:35-2A.10 deals with preceptorship programs for graduates of nurse midwife programs who are awaiting the results of the certifying examination. The Board proposes to delete this section as it believes that with expanded practice it should not allow applicants, who have not yet passed the certifying examination, to practice as midwives.

Existing N.J.A.C. 13:35-2A.11 is proposed for recodification as N.J.A.C. 13:35-2A.14. The Board proposes to delete subsections (c) and (d) which set forth a formulary of drugs which a certified nurse midwife with prescriptive authority can prescribe and prohibit certified nurse midwives from prescribing anything that was not on the formulary. In their place, the Board proposes new subsection (c) which allows certified nurse midwives with prescriptive authority to prescribe only those drugs which are categorized in the formulary of drugs established in clinical guidelines. Existing subsection (e) is recodified as subsection (d) and is amended to clarify language and delete a requirement that prevented the prescription of substances or devices not specified in written agreements. This provision is deleted because it is covered by proposed new subsection (c). Subsection (f), which outlines what a certified nurse midwife must include in a prescription, is deleted. The Board proposes new subsection (e) which requires that all prescriptions written by a CNM conform to N.J.S.A. 45:14-14 et seq. and N.J.A.C. 13:35-7.2. A reference which limited the use of certain drugs in the formulary to Licensed Health Care Facilities is also deleted as unnecessary since the formulary has been deleted.

N.J.A.C. 13:35-2A.15 is a proposed new rule which outlines requirements a licensee must meet in order to perform limited ultrasound examinations. Subsection (a) states that a licensee can perform limited ultrasound examinations if he or she completes a course as outlined in subsection (b). The rule also states that "limited ultrasound" means the use of ultrasound to: assess fetal number, fetal cardiac activity, fetal position and presentation, placental location, amniotic fluid parameters; biophysical profile parameters; uterine position; uterine size; the number and size of early gestational sac; and the presence and length of embryonic poles. Subsection (b) requires a licensee to complete a 12-hour course before performing limited ultrasound. The course must be given by a college or university accredited by an accrediting association recognized by the United States Department of Education or an organization that grants ACNM, ACOG, AMA-PRA or AOA category one continuing education units. Subsection (c) requires that course instruction include: ultrasound instrumentation; accountability of licensees; components of informed consent; anatomy and physiology relevant to limited ultrasound examinations; antepartum and intrapartum fetal surveillance and the formulation of a plan of care based on assessments made. The course also must include components of ultrasound examination which covers: fetal number; fetal cardiac activity; fetal position and presentation; placental location; amniotic fluid evaluation; and biophysical profile parameters. Finally, a course must include components of gynecological ultrasound examination which covers identification of uterine position, evaluation of uterine size, recognition of early fetal cardiac activity and assessment of number, size and location of early gestational sacs and presence and length of embryonic poles. Subsection (d) requires that licensees who perform limited ultrasound amend clinical guidelines to include circumstances when a licensee may perform limited ultrasound examinations.

Proposed new N.J.A.C. 13:35-2A.16 outlines requirements a certified nurse midwife or certified midwife must meet if he or she wishes to perform colposcopies. Subsection (a) states that a CNM or CM can perform colposcopies to evaluate and diagnose abnormal cervical findings when he or she has completed a course as outlined in subsection (b). Subsection (b) requires that a CNM or CM complete a 20-hour colposcopy course prior to performing a colposcopy. The course must be given by a college or university accredited by an accrediting association recognized by the United States Department of Education or given by an organization recognized by the American Society of Colposcopy and Cervical Pathology, the American College of Obstetrics and Gynecology, the American College of Nurse Midwives or the National Association of Nurse Practitioners in Reproductive Health. Subsection (c) requires a CNM or CM who intends to perform colposcopies to complete 50 colposcopies under the supervision of a CNM or CM who has already met the requirements of N.J.A.C. 13:35-2A.16 or an individual who has received education and training substantially similar to the requirements of N.J.A.C. 13:35-2A.16. Subsection (d) requires a CNM or CM who has completed a colposcopy course to maintain a certificate from the sponsor, indicating completion of the program. Subsection (e) requires a CNM or CM who intends to perform colposcopy to amend the clinical guidelines to include circumstances when the CNM or CM can perform colposcopy.

N.J.A.C. 13:35-2A.17 is a proposed new rule which outlines when a licensee may perform circumcisions. Subsection (a) allows a licensee who meets the requirements of subsections (b) and (c) to perform circumcisions. Subsection (b) requires a licensee who intends to perform circumcisions to complete a course given by a licensed physician or licensed midwife who has privileges to perform circumcisions in a licensed health care facility. The course shall include: the theory of circumcision; including benefits, risks and alternatives; providing informed consent to parents; indications and contraindications for circumcisions; and potential complications. Subsection (c) requires that a licensee observe five circumcisions and perform 20 circumcisions under the direct supervision of a physician or midwife qualified pursuant to N.J.A.C. 13:35-2A.17 prior to performing any circumcisions independently. "Direct supervision" means the presence of, and observation of the procedure by, a physician or midwife in the location where the circumcision is being performed. Subsection (d) states that a licensee who performs circumcisions must maintain documentation which indicates that he or she has met the requirements of subsections (b) and (c). Subsection (e) requires that licensees who intend to perform circumcisions include in the clinical guidelines circumstances when a licensee may perform circumcisions.

As the Board has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Board believes that the proposed amendments, repeals and new rules will have a beneficial impact on society. Proposed amendments to the rules specify the requirements for certified midwives and certified professional midwives to obtain a license to practice midwifery in the State. This increases the number of licensees available to consumers who wish to use the services of a midwife in New Jersey. In addition, clarification of rules which govern clinical guidelines and the scope of practice for licensees during the ante-, intra- and postpartum phases ensure that licensees will practice safely and effectively. Proposed new rules and amendments which allow certain licensees to perform limited ultrasound examinations, colposcopies and circumcisions ensure that patients may receive these services from midwives and ensure that midwives will perform these procedures safely and effectively.

Economic Impact

The Board believes that the proposed amendments, repeals and new rules may have an economic impact on midwife applicants and licensees. Amendments to N.J.A.C. 13:35-2A.4 require applicants to send the Board more information than existing rules require and the cost of providing this new information will be borne by applicants for licensure. Proposed new

N.J.A.C. 13:35-2A.7 requires licensees to pay a renewal fee when renewing licensure biennially. Proposed new rule N.J.A.C. 13:35-2A.10(b) requires that a licensee maintain certain equipment at the birth site during the intrapartum stage and the cost of obtaining this equipment will be borne by licensees. Proposed new rules N.J.A.C. 13:35-2A.15, 2A.16 and 2A.17 allow licensees to perform limited ultrasound examinations, colposcopies and circumcisions. Licensees who intend to perform these procedures must first take courses in these respective procedures. The cost of these courses will be borne by licensees.

Federal Standards Statement

A Federal standards statement is not required because there are no Federal standards or requirements applicable to the requirements of the proposed amendments, repeals and new rules.

Jobs Impact

The Board believes that the proposed amendments, repeals and new rules may increase jobs in the State. The amendments and new rules allow certified midwives and certified professional midwives to obtain licensure to practice midwifery in the State. This will facilitate the licensure of individuals who have not applied for licensure in many years.

Agriculture Industry Impact

The Board does not believe that the proposed amendments, repeals and new rules will have any impact on the agriculture industry of this State.

Regulatory Flexibility Analysis

If, for the purposes of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., the approximately 350 licensed midwives are deemed "small businesses," then the following analysis applies.

The Act requires the Board to set forth the reporting, recordkeeping and other compliance requirements of the proposal including the kinds of professional services likely to be needed to comply with the requirements. The Act further requires the Board to estimate the initial and annual compliance costs of the proposal with an indication of the varying impact on small businesses of differing types and sizes and to outline the manner in which the rules have been designed to minimize any adverse economic impact upon small businesses.

The costs imposed on small businesses by the proposed amendments, repeals and new rules are the same costs that are imposed on all businesses as outlined in the Economic Impact statement above.

The Board does not believe that licensees will need to employ any professional services to comply with the requirements of the proposed amendments and new rules.

The proposed amendments and new rules impose several compliance requirements. N.J.A.C. 13:35-2A.5(b) and (d) require licensees to conduct their practices pursuant to standards set forth by either the American College of Nurse Midwives or the North American Registry of Midwives. N.J.A.C. 13:35-2A.6 requires licensees to establish clinical guidelines with physicians that outline the licensee's scope of practice. These guidelines must be provided to the Board upon request and must be reviewed periodically. N.J.A.C. 13:35-2A.7 requires licensees to renew licensure biennially. N.J.A.C. 13:35-2A.9 requires a licensee to develop a management plan for any woman who meets articulated risk factors. N.J.A.C. 13:35-2A.10 requires that licensees ensure that at every birth site there is a person who is certified in Basic Life Support and Neonatal Resuscitation. Licensees must also ensure that there is oxygen equipment, a neonatal bag and mask, adult oxygen mask, suction equipment, IV fluids and oxtoxics at the birth site. N.J.A.C. 13:35-2A.11 requires that a birth take place in a hospital if certain risk factors are evidenced. The rule also requires that a licensee arrange for a transfer to a hospital and the presence of an affiliated physician if certain risk factors occur during a birth. N.J.A.C. 13:35-2A.14 limits a certified nurse midwife with prescriptive authority to prescribe those drugs categorized in a formulary in the clinical guidelines. The rule also requires that all prescriptions conform to N.J.S.A. 45:14-14 et seq. N.J.A.C. 13:35-2A.15 requires a licensee who intends to perform limited ultrasound examinations to complete a 12-hour course and to amend to clinical guidelines to indicate that the licensee can perform limited ultrasound examinations. N.J.A.C. 13:35-2A.16 requires certified nurse midwives and certified midwives who intend to perform colposcopies to complete a 20-hour colposcopy course, to complete 50 colposcopies under supervision and to amend clinical guidelines to indicate when a certified nurse midwife or certified midwife may perform colposcopies. N.J.A.C. 13:35-2A.17 requires a licensee who intends to perform circumcisions to complete a course in circumcisions, observe five circumcisions, perform 20 circumcisions under supervision and amend clinical guidelines to indicate when the licensee can perform circumcisions.

The proposed new rules also impose several reporting and recordkeeping requirements. N.J.A.C. 13:35-2A.6(d) requires licensees to file a notice with the Board identifying their affiliated physician and the physician's telephone number and business address. The licensee also must notify the Board within 30 days if the licensee changes affiliated physicians. A certified nurse midwife or certified midwife who successfully completes a colposcopy course must maintain a certificate from the sponsor of the course as part of his or her records. N.J.A.C. 13:35-2A.17 requires a licensee who intends to perform circumcisions to maintain documentation indicating that he or she has met the requirements of N.J.A.C. 13:35-2A.17(b) and (c).

The Board believes that since the proposal provides for the safe and effective practice of midwives, the amended and new rules should be applied uniformly to all licensees.

Smart Growth Impact

The Board does not anticipate that the proposed amendments, repeals and new rules will have any impact on the achievement of smart growth and implementation of the State Development and Redevelopment Plan, otherwise known as the State Plan.

Full text of the proposed repeals may be found in the New Jersey Administrative Code at N.J.A.C. 13:35-2A.1, 2A.2, 2A.4, 2A.5, 2A.6, 2A.8, 2A.9 and 2A.10.

Full text of the proposed amendments and new rules follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 2A. LIMITED LICENSES: [CERTIFIED NURSE] MIDWIFERY

13:35-2A.1 Midwifery practice

(a) The rules in this subchapter are intended to protect the health and safety of the public through licensure of midwives, pursuant to N.J.S.A. 45:10-1 et seq.

(b) This subchapter prescribes standards for midwifery licensure and for the renewal, suspension or revocation of that licensure.

13:35-2A.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Affiliated physician" means a person who holds a plenary license to practice medicine and surgery in New Jersey, issued by the Board, who adheres to clinical guidelines with a licensed midwife.

"Board" means the New Jersey State Board of Medical Examiners.

"Certified midwife (CM)" means a person who is not a registered nurse and who holds certification from the American College of Nurse Midwives Certification Council (ACC) or its successors.

"Certified nurse midwife (CNM)" means a person who is a registered nurse and who holds certification from the American College of Nurse Midwives (ACNM) or the ACC or their successors.

"Certified professional midwife (CPM)" means a person who holds certification from the North American Registry of Midwives (NARM) or its successor.

"Clinical guidelines" means a written agreement, signed by both the licensee and the affiliated physician, which sets forth patterns of care and which provides for consultation, collaboration, management and referral as indicated by the health status of a woman receiving care from a licensee.

"Committee" means the Midwife Liaison Committee of the New Jersey State Board of Medical Examiners.

"Licensee" means any person who holds a license from the Board to practice as a midwife.

13:35-2A.3 Midwifery Liaison Committee

(a) The Midwifery Liaison Committee shall consist of eight members who shall serve as consultants to the Board and who shall be appointed by the Board. The Committee shall include at least one certified nurse midwife, at least one certified professional midwife, at least one certified midwife, and two other midwives, all of whom

shall hold licensure from the Board. The Committee shall also include one certified nurse midwife who is a member of the Board and two physicians, one of whom shall be a member of the Board of Medical Examiners and one of whom shall be Board-certified by either the American Board of Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology or any other certification organization with comparable standards.

(b) The Board shall appoint each member for a term of three years. Committee members may be reappointed.

(c) Functions of the Committee shall include the following:

1. Advising and assisting the Board in the evaluation of applicants for midwifery licensure and certified nurse midwife applicants for prescriptive authorization;

2. Investigating complaints against licensees and unlawful conduct by licensees;

3. Approving professional education programs; and

4. Advising and assisting the Board in drafting and reviewing rules to govern midwifery practice.

13:35-2A.4 Application for licensure

(a) An applicant for licensure as a midwife shall submit to the Committee:

1. A completed application for licensure requesting information regarding the applicant's address, telephone number, date of birth and social security number;

2. Proof that the applicant is 18 years old or older;

3. An official transcript from a midwifery program, accredited by the American College of Nurse Midwives (ACNM) or the Midwifery Education Accreditation Council (MEAC), or their successors;

4. A notarized copy of Certification from either ACNM, ACC, NARM, or their successors;

5. The applicant's curriculum vitae;

6. Three photographs of the applicant, signed, dated and notarized; and

7. The application fee pursuant to N.J.A.C. 13:35-6.13(a)6i.

(b) Once the applicant has been approved, he or she shall submit the initial license fee pursuant to N.J.A.C. 13:35-6.13(a)6iv.

13:35-2A.5 Independent practice

(a) Certified nurse midwife and certified midwife practice shall include the provision of maternity care and well woman care within a health care system which provides for consultation, referral and collaboration, and:

1. For licensees without prescriptive authority, administering or dispensing those medications listed in the clinical guidelines; or

2. For licensees with prescriptive authority pursuant to N.J.A.C. 13:35-2A.14, prescribing, ordering, administering or dispensing medications.

(b) Certified nurse midwives and certified midwives shall conduct their practice pursuant to standards set forth by the ACNM in Standards for the Practice of Nurse Midwifery (1993), as amended and supplemented, available from the American College of Nurse-Midwives, 818 Connecticut Ave., Suite 900, Washington, DC 20006, which is incorporated herein by reference as part of this rule.

(c) Certified professional midwife practice shall include the provision of maternity care within a health care system which provides for consultation, referral and collaboration with a licensed physician and the administration or dispensing of those medications listed in the clinical guidelines.

(d) Certified professional midwives shall conduct their practice pursuant to standards set forth by the NARM in the Midwifery Model of Care (2000), as amended and supplemented, available from North American Registry of Midwives, 5257 Rosestone Drive, Lilburn, GA 30047, which is incorporated herein by reference as part of this rule.

13:35-[2A.3]**2A.6** [Minimum conditions of practice] **Affiliated physicians; clinical guidelines**

(a) Prior to beginning practice as a midwife, a licensee shall enter into an affiliation with a physician who is licensed in New Jersey and who:

1. Holds hospital privileges in operative obstetrics/gynecology;

2. Has a binding agreement with a physician who holds operative privileges in operative obstetrics/gynecology; or

3. Holds hospital privileges in gynecology, if a licensee limits his or her practice to non-obstetrical.

[(a)]**(b)** The [CNM] **licensee** shall establish written [agreements] **clinical guidelines** with [one or more] **the affiliated** physician[s] **which outlines the licensee's scope of practice.** [licensed in the State of New Jersey (hereinafter, the "affiliated physician(s)") who practice obstetrics and/or gynecology and who have hospital privileges in obstetrics and/or gynecology. The written agreements shall delineate the scope of practice of the CNM. In no instance, however, may the scope of practice of the CNM in any way exceed the scope of practice of the affiliated physician (as limited by the physician's privileges). All agreements shall include a written protocol setting forth:

1. All procedures and routine orders, including specific tests and treatment regimens, to be performed or provided by the CNM;

2. The circumstances under which consultation, co-management, referral and transfer of care of women and/or newborns between the CNM and the affiliated physician are to take place, and the mechanics by which each is to occur;

3. A list of all medications the CNM may dispense, administer, order and/or prescribe. Under no circumstances may the agreement provide for the use of controlled dangerous substances outside of a licensed hospital except upon prescription of the physician; and

4. A schedule setting forth or a mechanism for determining the availability of the physician (or a designated qualified substitute physician responsible for back-up care) for consultation and emergency assistance or medical management when needed.]

(c) The clinical guidelines shall set forth:

1. An outline of routine care;

2. Procedures the licensee will perform or provide;

3. Procedures to follow if one of the risk factors from N.J.A.C. 13:35-2A.9 and 2A.11 are encountered;

4. The circumstances under which consultation, collaborative management, referral and transfer of care of women between the licensee and the affiliated physician are to take place, and the manner by which each is to occur;

5. If the licensee is a certified nurse midwife with prescriptive authority pursuant to N.J.A.C. 13:35-2A.12, a formulary listing the categories of drugs, which may include controlled dangerous substances, the certified nurse midwife may order, prescribe, administer or dispense;

6. If the licensee does not hold prescriptive authority pursuant to N.J.A.C. 13:35-2A.14, a list of all medications the licensee may dispense or administer pursuant to the directions of the affiliated physician;

7. A mechanism for determining the availability of the affiliated physician, or a substitute physician, for consultation and emergency assistance or medical management when needed; and

8. The manner by which emergency care for newborns will be provided.

[(b)]**(d)** [The CNM shall file with the Board] **Prior to beginning practice, a licensee shall file with the Board** a notice [listing the name(s) and address(es) of] **identifying** the affiliated physician[(s) with whom the CNM establishes written agreements], **the physician's telephone number and business address** and the effective date of the [agreement(s) at the time of application for registration with the Board] **clinical guidelines.** In the event of any change of **affiliated** physician[(s)], the [CNM] **licensee** shall notify the Board in writing within [seven] **30** days of the change.

(e) Clinical guidelines shall be made available to the Board upon request.

[(c)]**(f)** The [CNM] **clinical guidelines** shall [participate in] **include provisions for** periodic conferences with the affiliated physician for review of patient records and for quality [assurance] **improvements.**

[(d) The CNM shall demonstrate a satisfactory peer review by a Peer Review Committee of the ACNM.

(e) The CNM shall function in accordance with the published Standards for the Practice of Nurse-Midwifery of the ACNM.]

(g) A licensee who practices without establishing clinical guidelines with an affiliated physician commits professional misconduct as proscribed by N.J.S.A. 45:1-21(e).

13:35-2A.7 Biennial renewal

(a) A license shall be renewed every two years.

(b) When renewing a license, the licensee shall submit to the Board:

1. A completed renewal form; and

2. The biennial registration fee pursuant to N.J.A.C. 13:35-6.13(a)6v.

13:35-2A.8 Antepartum management

(a) A licensee's scope of practice during antepartum stages includes:

1. Ordering medical, therapeutic and diagnostic measures in accordance with clinical guidelines; and

2. Identifying women with medical, obstetrical or gynecological risk factors outlined in N.J.A.C. 13:35-2A.9.

13:35-[2A.7]**2A.9** Management of antepartum women at **increased** risk

(a) [The CNM] **A licensee** may participate in the management of antepartum patients at **increased** risk under the following conditions:

1. The **affiliated** physician[/CNM team] **and licensee** shall have [both] agreed to include the [patient] **woman** at **increased** risk in the caseload;

2. The **affiliated** physician[/CNM team] **and licensee** shall have established **and documented** a management plan for all [patients] **women** identified as at **increased** risk, which [plan] shall delineate the role of both the **affiliated** physician and the [CNM] **licensee** in the care of the [patient] **woman**. The management plan shall set forth the following:

i. Frequency of physician visits;

ii. Timing of [appropriate] **indicated** diagnostic and evaluative procedures;

iii. [Parameters] **Specific parameters** for consultation; and

iv. A proposed plan for the [delivery] **birth**, including the type, place and provider.

3. [All patients at risk shall be classified as either Schedule "A" or Schedule "B" patients, in accordance with the schedules set forth in (a)4 and 6 below. The minimum standards of physician participation in the management of the at risk patient shall vary dependent upon whether the patient is classified as Schedule "A" or Schedule "B." The minimum standards of physician participation for Schedule "A" patients set forth in (a)5 below and for Schedule "B" patients in (a)7 below.] **The management plan shall be reviewed periodically by the licensee and the affiliated physician and revised when necessary.**

[4. Patients with the following risk factors shall be deemed to the Schedule "A" patients:]

(b) The following are risk factors that require management as outlined in (a) above:

[i. Documented problems in maternal medical history:]

1. Maternal health status:

[(1)]**i.** Acute and/or chronic hypertension;

[(2)]**ii.** Congenital or acquired heart disease;

[(3)]**iii.** [Deep vein thrombosis (current or recent history)] **Anti-phospholipid syndrome**;

[(4)]**iv.** HIV positive[, AIDS] or AIDS [Related Complex];

[(5)]**v.** [Renal] **Chronic renal** disease;

[(6) Severe urinary tract infection;]

[(7)]**vi.** Seizure disorder requiring medications;

[(8)]**vii.** [Hemolytic] **Chronic** anemia **and/or hemoglobinopathy**; [or

(9) Insulin dependence.]

viii. Diabetes mellitus;

ix. Drug addiction;

x. Psychosis;

xi. Asthmatic on daily oral medication;

xii. Any connective tissue disorder;

xiii. Multiple sclerosis;

xiv. History of cerebrovascular accident; or

xv. History of cancer.

[ii. Documented problems in past maternal obstetrical history:]

2. Maternal reproductive health history:

[(1)]**i.** Incompetent cervix;

[(2)]**ii.** Two or more second or third trimester fetal losses; [or]

[(3)]**iii.** Preterm [delivery; or] **labor and/or delivery;**

iv. Parity of six or more;

v. Previous cesarean delivery;

vi. Surgery involving the uterine wall;

vii. Previous placental abruption;

viii. Previous postpartum blood transfusion;

ix. Previous cervical surgeries including Loop Electrosurgical Excision Procedures (LEEP), cone biopsies or three or more surgical cervical dilitations; or

x. Intra-uterine growth restriction and/or delivery of an infant weighing less than 2,500 grams at 36 weeks or more.

[iii. Documented problems in present maternal obstetrical history:]

3. Current maternal obstetrical status:

[(1)]**i.** [Significant] **Obstructive** uterine myomata;

[(2)]**ii.** [Hydramnios] **Polyhydramnios** or oligohydramnios;

[(3)]**iii.** Isoimmunization;

[(4)]**iv.** Multiple gestation;

[(5)]**v.** Intrauterine growth [retardation] **restriction**; [or]

[(6)]**vi.** Current evidence of fetal chromosome [or other] disorder confirmed by amniocentesis [or ultrasound.] **and/or congenital anomaly;**

vii. Gestational diabetes;

viii. Maternal age less than 14 years or more than 40 years;

ix. PAP smear indicating dysplasia;

x. Placenta previa;

xi. Medicated pre-term labor; or

xii. Preeclampsia.

[5. For all patients classified within Schedule "A," the physician shall be in the office on each patient visit and shall review the care of the patient on each visit. Prior to the Schedule "A" patient's discharge from each scheduled visit, the physician shall review and sign the chart. The physician shall examine the Schedule "A" patient at least once during each trimester and, at that time, the management plan shall be reviewed and revised as necessary by the physician/CNM team.

6. Patients with the following risk factors shall be deemed to be Schedule "B" patients:

i. Documented problems in maternal medical history:

(1) Drug addiction;

(2) Psychotic episode;

(3) Controlled asthmatics currently on medication; or

(4) Hematologic disease;

ii. Documented problems in past maternal obstetrical history:

(1) Parity of six or more;

(2) Previous cesarean delivery;

(3) Surgery involving the uterine wall;

(4) Previous placental abruption;

(5) Previous significant postpartum hemorrhage; or

(6) Preterm labor; or

iii. Documented problems in present maternal obstetrical history:

(1) Any recent history or visible evidence of genital herpes;

(2) Gestational diabetes;

(3) No prenatal care prior to the 28th week;

(4) Maternal age less than 16 years or more than 35 years; or

(5) Significantly abnormal PAP smear.

7. For all patients classified within Schedule "B," the affiliated physician or his or her designee shall be available for consultation during hours of prenatal visits. The physician shall evaluate the management plan and current status of the Schedule "B" patient at least once each trimester. The plan shall be reviewed and revised as necessary by the physician/CNM team.

8. The patient at risk shall receive all scheduled prenatal care in a licensed ambulatory care clinic, a licensed hospital clinic or a professional office.]

13:35-2A.10 Intrapartum management

(a) A licensee's scope of practice during intrapartum stages includes:

1. Managing labor and birth for women not classified as being at increased risk pursuant to N.J.A.C. 13:35-2A.11, in accordance with clinical guidelines;

2. Performing immediate screening of the newborn and resuscitation of the newborn when necessary. The licensee shall refer newborns with acute medical conditions to a physician trained in the care of a newborn;

3. Performing an episiotomy;

4. Repairing first and second degree episiotomies and lacerations; and

5. Using local anesthesia.

(b) Every licensee shall ensure that at the birth site:

1. There is a person who is certified in Basic Life Support (BLS) and in Neonatal Resuscitation Program (NRP) by the American Academy of Pediatrics; and

2. The following equipment is present:

i. Oxygen;

ii. A neonatal bag and mask;

iii. An adult oxygen mask;

iv. Suction equipment;

v. IV fluids; and

vi. Oxytoxics.

(c) In addition to the tasks outlined in (a) above, a Certified Nurse Midwife (CNM) or Certified Midwife (CM) may:

1. Repair third degree lacerations upon the direction of the affiliated physician;

2. Repair fourth degree lacerations under the direct supervision of a physician who has hospital obstetrical privileges; and

3. Administer pudendal anesthesia in a licensed healthcare facility, which includes birthing centers. No licensee shall administer pudendal anesthesia in any other setting.

13:35-2A.11 Management of intrapartum women at increased risk

(a) If a woman receiving care from a licensee evidences any of the following conditions, the licensee shall only participate in the birth if it takes place in a licensed hospital:

1. Pre-term labor less than 37 weeks. If pre-term labor is less than 34 weeks, an affiliated physician shall be present at the birth;

2. Premature rupture of membranes more than 24 hours before onset of regular contractions;

3. Assessment of infant weight less than 2,500 grams or more than 4,500 grams;

4. Vaginal birth after previous cesarean delivery;

5. The need for prescriptive medication to induce or augment labor;

6. Post-datism (greater than 42 weeks completed gestation);

7. Multiple gestation;

8. Malpresentation; or

9. Evidence of chorioamnionitis.

(b) If a woman receiving care from a licensee evidences the following during the intrapartum phase the licensee shall arrange for the presence of an affiliated physician at the hospital; or, if the woman is not in a hospital, arrange for the immediate transfer of the woman to a hospital obstetric unit:

1. Development of hypertension or preeclampsia;

2. Non-reassuring fetal heart pattern, unresponsive to conservative measures;

3. Prolapse of cord;

4. Intrapartum hemorrhage;

5. Multiple gestation;

6. Malpresentation; or

7. Any condition requiring operative intervention.

13:35-2A.12 Postpartum care

(a) A licensee's scope of practice during the postpartum stage includes:

1. Assessment and treatment; and

2. Contraceptive services.

13:35-2A.13 Well woman care

(a) A certified nurse midwife or certified midwife may provide well woman care throughout the life cycle which shall include:

1. Gynecological and primary health care screening, assessment and treatment; and

2. Contraceptive services.

13:35-[2A.11]**2A.14** Prescriptive authorization

(a)-(b) (No change.)

[(c) The Board has established a formulary of drugs which may be ordered, administered, prescribed or dispensed by CNMs who have prescriptive authorization. The formulary shall be reviewed, amended if deemed necessary, and published periodically. The formulary consists of:

Analgesics (IV**, IM**, PO**)
Narcotics**
Non-narcotic
Anesthetics
Injectable (Local/Pudendal)
Topical
Antacids
Antihelmintics (Topical)
Antibacterials (IV**, IM, PO, Topical)
Antiseptics (IV**, IM, PO, Topical)
Antibiotics (IV**, IM, PO, Topical)
Antihistamines
Antivirals
Anti-Emetics
Barbiturates (IV**, IM**, PO**)
Contraceptives hormonal
Devices
Topical
Barriers
Cough and Cold Preparations
Non-narcotic
Fungicides (Topical)
Hematinics
Hemorrhoidal Preparations
Hormones
Laxatives
Mineral Supplements
Oxytocics (IVII, IM, PO, Topical)
Parenteral Fluids**
Pre-Eclamptic Drugs**
Prostaglandin Gels**
RH—Immune Globulin
Stool Softeners
Tocolytics-Parenteral** (PO)
Topical
Moisturizers
Cleansers
Therapeutic Shampoo/lotion/cream
Steroids
Vaccines
Vaginal Preparations
Vitamins

(d) A CNM who is authorized to prescribe drugs may prescribe only those drugs which are specified within the formulary of drugs established by the Board. In no case may the written agreement with a licensed physician that CNM is required to maintain pursuant to N.J.A.C. 13:35-2A.3 include any substance or device not specified within the formulary.]

(c) A CNM who is authorized to prescribe drugs may prescribe only those drugs which are categorized in the formulary of drugs established in the clinical guidelines.

[(e)]**(d)** A CNM's authorization to prescribe drugs, medicine, or devices may, upon notice and an opportunity for a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., be revoked or otherwise limited by the Board if the CNM:

1. Fails to maintain current licensure and registration with the Board;

2. Fails to maintain **certification in good standing with the** ACNM or ACC [certification in good standing]**, or their successors**;

3. Uses prescriptive authorization for other than therapeutic purposes; **or**

4. Uses prescriptive authorization to prescribe substances or devices not included [within] **in** the formulary of drugs established [by the Board; or] **in the CNM's clinical guidelines.**

[5. Uses prescriptive authorization to prescribe substances or devices not specified within any written agreement maintained pursuant to N.J.A.C. 13:35-2A.3 or for purposes not intended with any written agreement.

(f) A CNM shall provide the following on all prescription blanks:

1. The CNM's full name, identification of professional practice, license number, prescriptive authorization number, address and telephone number. This information shall be printed or stamped on all prescription blanks;

2. The affiliated physician's full name, printed or stamped;

3. The full name, age and address of the patient;

4. The date of the issuance of the prescription;

5. The name, strength and quantity of drug or drugs to be dispensed and route of administration;

6. Adequate instruction for the patient. A direction of "p.r.n." or "as directed" alone shall be deemed an insufficient direction;

7. The number of refills permitted or time limit for refills, or both;

8. The signature of the prescriber, hand-written; and

9. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the CNM's initials next to the chosen option, in addition to the space required for the signature in (f)8 above.]

(e) Prescriptions written by a CNM shall conform to the dictates of N.J.S.A. 45:14-14 et seq. and N.J.A.C. 13:35-7.2.

[**Administered in Licensed Health Care Facilities only.]

13:35-2A.15 Limited ultrasound examination

(a) A licensee who has completed a course as required in (b) below may perform a limited ultrasound examination. For purposes of this section, "limited ultrasound" shall mean the use of ultrasound to assess any of the following: fetal number, fetal cardiac activity, fetal position and presentation, placental location, amniotic fluid parameters, biophysical profile parameters, uterine position, uterine size, the number and size of early gestational sac and the presence and length of embryonic poles.

(b) A licensee who wishes to perform limited ultrasound shall complete a 12-hour course given by a college or university accredited by an accrediting association recognized by the U.S. Department of Education or an organization which grants ACNM, American College of Obstetrics and Gynecology (ACOG), American Osteopathic Association (AOA) or American Medical Association-Physicians Recognition Award (AMA-PRA) category one continuing education credits.

(c) Limited ultrasound course instruction shall include:

1. Ultrasound instrumentation;

2. Accountability of the licensee;

3. Components of informed consent;

4. Principles of anatomy and physiology relevant to limited ultrasound examinations;

5. Elements of antepartum and intrapartum fetal surveillance;

6. Components of ultrasound examination:

i. Fetal number;

ii. Fetal cardiac activity;

iii. Fetal position and presentation;

iv. Placental location;

v. Amniotic fluid evaluation; and

vi. Biophysical profile parameters;

7. Components of gynecological ultrasound examination:

i. Identification of uterine position;

ii. Evaluation of uterine size;

iii. Assessment of number, size and location of early gestational sac(s) and presence and length of embryonic pole(s); and

iv. Recognition of early fetal cardiac activity; and

8. Formulation of a plan of care based on assessments made, including the need for consultation, referral and follow-up.

(d) A licensee who intends to perform limited ultrasound examinations pursuant to (a) above shall amend the clinical guidelines to include circumstances when the licensee may perform limited ultrasound examinations.

13:35-2A.16 Colposcopies

(a) A CNM or CM who has completed a course as required by (b) below and clinical experience required by (c) below may perform colposcopies for the purposes of evaluating and diagnosing abnormal cervical findings.

(b) A CNM or CM who wishes to perform colposcopies shall complete a 20-hour colposcopy course, given by a college or university accredited by an accrediting association recognized by the U.S. Department of Education or given by an organization recognized by either the American Society of Colposcopy and Cervical Pathology, the American College of Obstetrics and Gynecology, the American College of Nurse Midwives or the National Association of Nurse Practitioners in Reproductive Health.

(c) A CNM or CM who intends to perform colposcopies independently shall first complete 50 colposcopies under the supervision of a CNM or CM who has met the requirements of this section or an individual who has received education and training substantially similar to that required by this section.

(d) A CNM or CM who has successfully completed a colposcopy course shall maintain a certificate from the sponsor of the colposcopy course indicating that the CNM or CM has completed the course.

(e) A CNM or CM who intends to perform colposcopy pursuant to (a) above shall amend the clinical guidelines to include circumstances when the midwife may perform colposcopy.

13:35-2A.17 Circumcisions

(a) A licensee who has completed a course as required by (b) below and clinical experience as outlined in (c) below may perform circumcisions.

(b) A licensee who intends to perform circumcisions shall complete a course given by a licensed physician or licensed midwife who has privileges to perform circumcisions in a licensed health care facility. The circumcision course shall include:

1. The theory of circumcisions, including the procedure's benefits and risks, and alternatives to the procedure;

2. Providing informed consent to the parents;

3. Indications and contraindications for circumcision; and

4. Potential complications.

(c) Prior to performing any circumcisions independently as permitted by this section, the licensee shall observe five circumcisions and perform 20 circumcisions under the direct supervision of a licensed physician or a midwife qualified to perform independently pursuant to this section. For purposes of this subsection, "direct supervision" means the presence of, and observation of the procedure by, a licensed physician, or midwife qualified to perform circumcisions, in the location where the circumcision is being performed.

(d) A licensee who intends to perform circumcisions pursuant to (a), (b) and (c) above shall maintain, as part of the licensee's records, documentation which indicates that the licensee has met the education requirements of (b) and (c) above.

(e) A licensee who intends to perform circumcisions pursuant to (a), (b) and (c) above shall amend the clinical guidelines to include circumstances when the licensee may perform circumcisions.